

10, 1998. The certified copy of this priority application was filed in the international application during the international stage based upon the filing of the Japanese priority application. A copy of PCT Form PCT/IB/304 was sent to the U.S. PTO during the international stage. An additional copy of PCT/IB/304 was filed in the PTO on June 8, 2001, when filing the present national phase application.

Accordingly, please acknowledge that the certified copy of the priority application was received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

Claims 8, 9 and 10 have been amended as shown above to overcome the rejection under 35 USC 112, second paragraph, as supported in the present specification, including at page 11, lines 1-8.

Claims 3, 7 and 11 have been amended as shown above in order to correctly indicate weight percent ("wt%") in response to the rejection under 35 USC 112, second paragraph.

Claims 13-18 have been amended as shown above, in response to the rejection under 35 USC 101, by formatting the claims into statutorily proper method claims.

No new matter has been added.

Claims 3, 4, 7-11 and 12 stand rejected under 35 USC 112, second paragraph.

With respect to the rejection of claims 3, 7 and 11, and in particular, the term "at least 30%" these claims have been amended to show the standard unit of "wt%." The recited 30 wt% of xylobiose is supported in the specification, including at page 14, lines 12-13. The xylooligosaccharide used in Example 1

contained about 42 wt% of xylobiose, as disclosed at page 18, lines 18 - 19.

The xylooligosaccharide used in Example 3 contained about 34 wt% of xylobiose, as disclosed at page 19, lines 2 - 4. The present specification discloses that xylobiose shows therapeutic activity, such as blood ammonia lowering activity, therapeutic activity for hyperammonemia and therapeutic activity of hepatic encephalopathy (see page 12, lines 3-13 of the specification).

According to the present application, xylobiose is an effective ingredient, but xylooligosaccharide containing xylobiose as a main ingredient, for example that containing at least 30% by weight of xylobiose, can also be useful as an active and effective ingredient for therapeutic purposes.

Referring again to the examples in this application, xylooligosaccharides used in Examples 1 and 3 contained about 42 wt% and 34 wt% of xylobiose, respectively. In Examples 4 and 5, xylooligosaccharide was employed which was the same as that in Example 3. In Example 2, pure xylobiose was used. The results of the examples show that the efficacy of xylooligosaccharide containing at least 30 wt% of xylobiose is the same as that of pure xylobiose. The xylooligosaccharide could thus contain 100 wt% of xylobiose.

With respect to the recited phrase in the claims of "a pharmaceutically acceptable carrier" it is axiomatic that this phrase is well accepted claim language in the pharmaceutical arts. Moreover, the phrase is supported in the present specification, including at page 15, lines 12-24.

In response to the rejection of claims 8-10, these claims have been amended to recite the related pharmacological activity, which further lends patentable distinction of these claims from claim 2.

The applicants submit that all presently considered claims are fully allowable under Section 112, second paragraph.

In response to the rejection of claims 13-18 under 35 USC 101, these claims have been amended as shown above to be in the statutorily proper format of a method claim. Withdrawal of this rejection is respectfully requested.

The applicants respectfully traverse the rejection of claims 1-12 under 35 USC 102(b) in view of Mitsuhashi et al. This reference does not anticipate the present claimed invention or make it obvious.

Mitsuhashi discloses a growth promoting agent which contains pullulan and/or dextran to promote the growth of bifid bacteria (see page 2, lines 8-12). That is, Mitsuhashi discloses a growth-promoting agent for bifid bacteria which contains as an effective ingredient, pullulan, dextran or mixture thereof. In Mitsuhashi, oligosaccharide can be added to the agent for greatly promoting the growth of bifid bacteria. In the abstract and in claims 5 and 7 of Mitsuhashi, xylooligosaccharide is merely exemplified as one of many oligosaccharides.

In contrast, the presently claimed invention recites an agent for lowering blood ammonia, a therapeutic agent of hyperammonemia and a therapeutic agent of hepatic encephalopathy, which agents comprise xylobiose or xylooligosaccharide containing at least 30 wt% of xylobiose as an effective ingredient.

Mitsuhashi does not disclose or suggest a therapeutic agent containing xylobiose or xylooligosaccharide containing at least 30 wt% xylobiose, nor that such agent is effective for the recited therapeutic uses.

Accordingly, the applicants submit that the presently claimed invention is nowhere disclosed, suggested or made obvious by the teachings of

Mitsuhashi. The presently claimed invention is not only allowable under Section 102(b), but is also allowable under Section 103(a) in view of the cited art.

In view of the above, it is believed that this application is in condition for allowance and a Notice to that effect is respectfully requested.

Respectfully submitted,

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## APPENDIX

### VERSION WITH MARKINGS TO SHOW CHANGES MADE

#### IN THE CLAIMS:

Proposed Amendments To Claims 3, 7, 8, 9, 10, 11 and 13-18 Showing  
Deletions And Insertions.

Claim 3. (Amended) The blood ammonia lowering agent according to claim 2, wherein said xylooligosaccharide contains at least [30%] 30 wt% of xylobiose.

Claim 7. (Amended) The therapeutic agent of hyperammonemia according to claim 6, wherein said xylooligosaccharide contains at least [30%] 30 wt% of xylobiose.

Claim 8. (Twice Amended) The therapeutic agent of hyperammonemia according to claim 5, which comprises said xylobiose or said xylooligosaccharide and a pharmaceutically acceptable carrier, wherein said therapeutic agent has the activity of promoting the growth of organic acid producing enterobacteria.

Claim 9. (Amended) A therapeutic agent of hepatic encephalopathy [containing] comprising xylobiose as an active ingredient, wherein said therapeutic agent has the activity of promoting the growth of organic acid producing enterobacteria.

Claim 10. (Amended) The therapeutic agent of hepatic encephalopathy according to claim 9, which [contains] comprises xylooligosaccharide, said xylooligosaccharide [containing] comprising said xylobiose as a main ingredient, wherein said therapeutic agent has the activity of promoting the growth of organic acid producing enterobacteria.

Claim 11. (Amended) The therapeutic agent of hepatic encephalopathy according to claim 10, wherein said xylooligosaccharide contains at least [30%] 30 wt% of xylobiose.

Claim 13. (Amended) [Use of xylobiose] A method for producing a blood ammonia lowering agent by employing xylobiose as an active therapeutic ingredient.

Claim 14. (Amended) [Use of xylooligosaccharide containing xylobiose as a main ingredient] A method for producing a blood ammonia lowering agent by employing xylooligosaccharide, containing xylobiose as a main ingredient, as an active therapeutic ingredient.

Claim 15. (Amended) [Use of xylobiose] A method for producing a therapeutic agent of hyperammonemia by employing xylobiose as an active therapeutic ingredient.

Claim 16. (Amended) [Use of xylooligosaccharide containing xylobiose as a main ingredient] A method for producing a therapeutic agent of hyperammonemia by employing xylooligosaccharide, containing xylobiose as a main ingredient, as an active therapeutic ingredient.

Claim 17. (Amended) [Use of xylobiose] A method for producing a therapeutic agent of hepatic encephalopathy by employing xylobiose as an active therapeutic ingredient.

Claim 18. (Amended) [Use of xylooligosaccharide containing xylobiose as a main ingredient] A method for producing a therapeutic agent of hepatic encephalopathy by employing xylooligosaccharide, containing xylobiose as a main ingredient, as an active therapeutic ingredient.